DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

G 42129

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

Via Federal Express

Our Reference: 2911003

August 5, 2003

Mr. Francis Guidici
President
LA Hearne Company
512 Metz Road
King City, CA 93930

WARNING LETTER

Dear Mr. Guidici:

An inspection of your licensed medicated feed manufacturing facility located on Cattleman Road, San Lucas, CA on March 18 and 25, 2003, by Food and Drug Administration (FDA) has revealed significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds (Title 21 Code of Federal Regulations (CFR), Part 225). Such deviations cause the medicated feeds manufactured at your mill to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act. The following deviations were observed during our investigation:

You failed to conduct potency assays on at least [redacted] representative samples of each feed requiring a medicated feed mill license at periodic intervals during the calendar year 2002 as required by 21 CFR 225.58(b)(1).

You failed to assure that all scales and metering devices are tested for accuracy at least once a year, or more frequently as may be necessary to insure their accuracy as required by 21 CFR 225.30(b)(4).

You failed to prepare and maintain a receipt record for each lot of drug received as required by 21 CFR 225.42(b)(5).

You failed to record the actual quantity of medicated feed produced in your production records as required by 21 CFR 225.102(b)(2)(iv).

You should take prompt action to correct these cGMP violations, and you should establish and implement procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure, injunction, and/or notice of opportunity for a hearing on a proposal to withdraw approval of your Medicated Feed Mill License under Section 512(m)(4)(B)(ii) of the Act and Title 21, Code of Federal Regulations, Part 515.22(c)(2). (This letter constitutes official notification under the law.) Based on the results of the March 18 and 25, 2003 inspection, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feeds are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drugs therein. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies.

Within fifteen days of the receipt of this letter, notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Russell A. Campbell, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, CA 94502.

Sincerely yours,

Charles D. Moss, Acting DD

Per Dennis K. Linsley
District Director